

REMARKS

Entry of this amendment and reconsideration of the above-referenced application is respectfully requested. Claims 1-3 and 40-52 are pending in the application.

The Office Action objected to Claim 50 alleging that the recitation “applying a hold down force . . . in the range of 0.5-1 kg” is inappropriate holding that units of mass are recited instead of force. Applicants take this opportunity to clarify Applicants’ use of kg units. Force, when measured in kg units, is an assumption under the framework of ideal gravity. Under such assumptions, 0.5 kg and 1.0 kg would translate to 4.9N and 9.8N, respectively - - the same forces exerted by a 0.5 kg and 1.0 kg weight onto the ground. Applicants respectfully submit that Applicants’ use of kg units would be understood by one skilled in the art to which the invention relates, and requests the Examiner to remove the objection in light of this clarification.

The Office Action also rejected pending Claims 1-3 and 46-52 as being allegedly unpatentable over the Imprint reference (WO 00/09184) in view of the Kheiri reference (USPN 6,364,889). The Office Action alleges that the Imprint reference discloses an apparatus for delivering a substance having one or more needles driven at a high velocity for reducing the amount of pain experienced by the recipient of the substance. The apparatus delivers an agent by needles that are driven by an impact applicator at a velocity of 1-100 m/s into the skin. Given the disclosed mass of the needle and moving parts at 0.3-1 g, the Office Action concludes the impact energy is 0.05-3 Joules/cm². The Office Action admits that the Imprint reference does not teach striking the stratum corneum in no greater than 10ms as recited by the pending claims. However, the Examiner has concluded “it would have been obvious to incorporate the teaching of the Kheiri reference regarding the timing of the in-stroke into the invention of the Imprint reference because both devices are directed to reducing the pain experienced by a patient.

Applicants have reviewed the references cited by the Office Action and are of the opinion that it would not have been obvious to combine the teachings of the Kheiri reference into the invention of the Imprint reference to arrive at the claimed invention. While both references provide discussion about the usefulness of reducing pain, there is no motivation to modify the Imprint impact applicator to strike the stratum corneum with an impact energy of 0.05-3 Joules/cm² in less than 10 m/s to obtain the benefits and unexpected advantages represented by the present invention.

As attested to by Dr. Robert Stone, in the declaration filed in Applicants Amendment B response, the specification clearly discloses several significant stated unexpected advantages from applying the microprotrusion member to the stratum corneum with the claimed impact energy. These unexpected advantages include the benefit of creating a uniform, effective and consistent penetration of the stratum corneum by a microprotrusion member, and increased rate of agent delivery. The motivation in the claimed subject matter for striking the stratum corneum with an impact energy of 0.05-3 Joules/cm² in less than 10 m/s is not driven by pain reduction since the microprotrusions in many instances form microslits in the stratum corneum of a length less than 150 um. The stratum corneum is a layer of dead tissue that do not have nerve endings.

The Imprint reference actually teaches away from the idea of using higher velocities in connection with its injectable needles to avoid pain. On page 2 of the Imprint reference, it is recognized in the art that driving a needle at high velocities is used to reduce pain, but states that the use of the very high speeds reflected in the Imprint reference had not been previously disclosed. If the Imprint reference already reduces pain by increasing the speed of needle delivery, there would have been no motivation to further increase the speed at which a needle strikes the stratum corneum, particularly striking the stratum corneum with an impact energy of 0.05-3 Joules/cm² in less than 10 m/s as required by the pending claims.

While the Imprint reference states on page 3 the needles can be driven to a depth of 10 microns and upward, the Imprint reference is not directed to the use of needles of the length employed by Applicants claimed invention. In fact, the Imprint references provides on page 3 that the needle can be driven through the skin to inject a substance into the subcutaneous layer, e.g. to a depth of 10 to 12 mm. In order to reach the subcutaneous layer one must first pass the stratum corneum, the dermis and the epidermis. So the Imprint reference's needle must be long enough to not only pass through all these other layers, but the needle must also be long enough to drive to a further depth of 10 to 12 mm. It is because of this depth of penetration that the Imprint reference requires a mechanism to avoid pain. The Imprint reference is not concerned with the advantages offered by the claimed invention, namely that the benefit of creating a uniform, effective and consistent penetration of the stratum corneum by a microprotrusion member, and increased rate of agent delivery.

Applicants are of the opinion, therefore, that one skilled in the art would not have been motivated the combine the Imprint and Kheiri references. Further, even if one were to combine

the Imprint and Khieri references and modify the Imprint apparatus to have the in-stroke speed of the Khieri apparatus, one skilled in the art would not have expected to achieve the advantages of Applicants' claimed invention.

Conclusion

In view of the above amendments and remarks, Applicants submit that Claims 1-3 and 46-52 are in condition for allowance. Therefore, a Notice of Allowance is respectfully requested. If the Examiner believes a telephone conference would expedite the prosecution of the present application, the Examiner is encouraged to call the undersigned at (650) 564-5887.

Respectfully submitted,



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